VENABLE® LLP

Claiming to be the Best:
Understanding How to Substantiate Your Claims

VENABLE® LLP

Agenda

- Brief Overview of Regulatory Agencies and Self-Regulatory Bodies
- What Is a Claim?
- Claim Substantiation Requirements
- Why Context Is Key
- Enforcement Trends

VENABLE® LLP

CLAIM SUBSTANTIATION: THE PLAYERS

National Advertising Division®

ERSP

State Attorneys General

VENABLE® LLP

Federal Regulatory Agencies

- **U.S. Food & Drug Administration (FDA):** primary responsibility for ensuring the safety of foods, cosmetics, dietary supplements, drugs, biologics, and medical devices in the U.S. under the Food, Drug, and Cosmetics Act (FDCA).

- **Federal Trade Commission (FTC):** authority over advertising for food, dietary supplements, cosmetics, over-the-counter (OTC) drugs, and many medical devices – under the Federal Trade Commission Act (FTCA).

VENABLE® LLP

Primary Jurisdiction?

- Pursuant to a liaison agreement, FDA has primary responsibility for the labeling of FDA-regulated products (including foods, dietary supplements, cosmetics) while FTC has primary responsibility for advertising.
- Not so black-and-white in application:
  - FDA will look to advertising as evidence of "intended use"
  - FTC has taken to evaluating whether claims are appropriate for product classification

VENABLE LLP

Overview of FTC

- The FTC regulates food and dietary supplement advertising claims and expects that advertisers have "competent and reliable scientific evidence" in support of claims made.
- Advertisers must be able to substantiate all reasonable interpretations of their claims
- The FTC may challenge an advertisement based on the fact that it is:
  - False or deceptive
  - Likely to mislead reasonable consumers
  - Likely to influence consumer purchasing decisions or otherwise affect important consumer decisions

VENABLE LLP

Overview of FDA

- FDCA also requires that a company possess substantiation that a claim is truthful and not misleading.
- FDA applies a standard consistent with the FTC approach.

NAD and ERSP

- The National Advertising Division (NAD) of the Council of Better Business Bureaus and the Electronic Retailing Self-Regulation Program (ERSP) are self-regulatory bodies that review factual claims for truthfulness and accuracy.
- Both offer alternative dispute resolution and provide written decision, typically within 60 business days.
- Accept cases involving:
  - Product performance claims
  - Superiority claims against competitive products
  - Scientific and technical claims
- Compliance with findings is voluntary, but…

National Advertising Division®

State Attorneys General (AGs)

- Enforce state mini- FTC Acts
  - Prohibit deceptive advertising and trade practices

What is a Claim?

- A claim is an explicit or implicit statement that a product has a certain benefit.
  - Express and implied claims are held to the same standard.
  - Claims are identified by assessing the “net impression” conveyed by all elements of an advertisement or label, including text, product name and depictions.
  - Includes statements made in testimonials.

- Types of claims include:
  - Overall Health and Wellbeing
  - Structure/Function Claims
  - Health Claims
  - Nutrient Content Claims
  - Comparative Claims

VENABLE® LLP

Structure/Function Claims

Structure/Function claims can:

(1) describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans ("calcium builds strong bones");

(2) characterize the action by which a nutrient or dietary ingredient maintains such structure or function, ("fiber helps maintain digestive regularity")

OR

(3) describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread the disease is in the United States.

VENABLE LLP

Health Claims

Claims discussing the relationship between a nutrient and a disease or disease condition.

- Language is specifically approved by FDA—based on:
  - Significant scientific agreement based on the totality of publicly available scientific evidence.
  - Authoritative statement by a federal scientific body or the National Academy of Sciences.
- Claim cannot deviate from approved language.

Ex: "Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis." (21 C.F.R. § 101.72)

VENABLE LLP

Health Claims

Qualified Health Claims

- Characterize the relationship between a nutrient and a disease condition, but they can be based on less than significant scientific agreement.
- Claim language discloses the limitations of evidence in support of the claimed relationship.
- Cannot deviate from FDA-approved language.

Ex: "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of X provides Y gram(s) of EPA and DHA omega-3 fatty acids."

VENABLE LLP

Nutrient Content Claims

Nutrient Content Claims characterize the level of nutrients in a product. E.g., “low fat,” “low sodium,” “excellent source of vitamin C”.

- Examples of nutrient content claims that are not approved by FDA:
  - “Low carb,” or any similar claim. Even a product name such as “Carb-Low” *may* trigger enforcement as an impermissible implied claim.
  - Synonyms for approved claims that have not been specifically approved by the agency.

Comparative Claims

- FTC View:
  - Comparative claims are permissible.
  - Must be comparing like products– requires clarity to avoid deception of the consumer.

- Competitors:
  - Litigation: The Lanham Act, Section 43(a)
  - Self-Regulation: National Advertising Division of the Council of Better Business Bureau (NAD)
  - Potential for significant legal expenses.

Claim Substantiation

- FTC and FDA require "competent and reliable scientific evidence" to substantiate all claims used in advertising and structure/function claims used on labels.
- "Competent and reliable scientific evidence" =
  - Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area,
  - That have been conducted and evaluated in an objective manner by persons qualified to do so,
  - Using procedures generally accepted in the profession to yield accurate and reliable results.

VENABLE® LLP

Claim Substantiation

- Factors Affecting Required Levels of Substantiation:
  - Type of product
  - Type of claim
  - Benefits of truthful claim
  - Consequences of false claim
  - What qualified experts in field believe is reasonable
  - Is specific level of support stated or suggested in the claim?

Claim Substantiation

- Advertising Claims
  - More often than not, advertising claims will not suggest that a certain level of support exists for a claim. In this situation, the level of scientific support necessary to substantiate a claim depends on the amount of research experts in the field would consider adequate to establish the claim's truthfulness.

Note: It would be an unusual occasion where one or two small studies will substantiate a claim.

Claim Substantiation

- In considering the number and type of studies required to substantiate a claim, advertisers should consider:
  1. The meaning(s) of the claims being made, express and implied;
  2. The relationship of the evidence to the claim;
  3. The quality of the evidence; and
  4. The totality of the evidence.
  5. Accepted norms in the relevant research field.

Claim Substantiation

- **Acceptable Scientific Evidence:**
  - Well-controlled, double-blind studies are likely to be given more weight than non-blind studies;
  - Longer-term studies are better than short-term studies;
  - Study's result should be statistically significant;
  - Nature and quality of the written report is important;
  - Studies published in reputable peer-reviewed scientific journals are looked upon with favor;
  - Studies not published in peer-reviewed journals may be used to substantiate claims if they would be considered properly designed and controlled by experts in the field.

Claim Substantiation

- **Scientific Evidence Must Be Relevant**
  - Evidence must be relevant to specific claim
  - Study endpoints must match claim
    - Ensure that you understand meaning of claim to determine what endpoints are relevant.
  - Consider: dose, dosage form, route of administration, formulation, total length of exposure, frequency of exposure, study population
  - Foreign Research
    - Note that differences between populations, such as differences in diet, general health, or patterns of use, could confound results.

Claim Substantiation

Issues with Other Types of Scientific Evidence

- FDA View: Alone, items listed below generally will not substantiate claims:
  - Animal Studies– best if based on data from studies in appropriate animal models, on data that have been reproduced in different laboratories, and on data that gives a statistically significant dose-response relationship.
  - In vitro Studies– best if based on data that has been reproduced in different laboratories.
  - Testimonial/Anecdotal Evidence– "honest opinion" not enough (discussed later)
  - Meta-analysis– may identify relevant reports, which may provide substantiation
  - Product monographs– may provide background information useful to understand relationship between substance and claimed effect

Claim Substantiation

Anecdotal, Traditional and Historical Use

- Anecdotal evidence, *alone*, cannot be used to substantiate a claim even if an individual's experience is true.
- Anecdotal evidence, however, *in connection with* a few well-controlled studies may be sufficient to substantiate a claim.
- A claim based solely on traditional and historical use must so state.
- Traditional and historical claims for serious diseases are not permitted.

Claim Substantiation

Claims Based on Traditional and Historical Use

- Present in way that consumers understand that sole basis for claim is a history of use of product for a particular purpose.
- Dosage form, route of administration, and the like, must match the traditional use.
- Some claims may not be used, even if qualified:
  - Claims that present substantial risk of injury to consumer health or safety if unfounded
    - Could lead consumer to forego proven treatments and self-medicate for serious condition
    - Permissible: “Ancient folklore remedy used for centuries by Native Americans to aid digestion.”
    - Impermissible: “American folk remedy for shrinking tumors.”

VENABLE® LLP

Special Considerations for Comparative Claims

- Take caution in providing editorial comment on the comparative formulations. Preference is to not name the comparative products.
- Often must have head-to-head studies to substantiate.

VENABLE® LLP

Context Is Key

- The context in which the claim appears is extremely important
  - E.g., Not a health claim, but a statement of dietary guidance: “A diet rich in fruits and vegetables may reduce the risk of coronary heart disease.”
  - No reference to a specific substance.
  - Do not include graphics depicting medicine or heart health.
  - Must be truthful and not misleading.

VENABLE LLP

Testimonials and Expert Endorsements

- Testimonials and expert endorsements for supplements that pertain to the health benefits of a product **must be substantiated as though they were made by the marketer itself, or properly disclaimed**.
- A testimonial or endorsement must represent the experience that a typical consumer can expect with the product, or be properly disclaimed
  - There is no personal opinion exception.
  - Must reflect the honest opinions, findings, beliefs, or experience of the endorser.
  - Any material connection between the endorser and the seller must be disclosed.

Testimonials and Expert Endorsements

- **Disclaimers: FTC's View**
  - If a marketer's substantiation does not demonstrate that the results attested to in a testimonial are representative, then a clear and conspicuous disclaimer is necessary.
  - Marketer should either state what the generally expected results would be or indicate that the consumer should not expect to experience attested results.
    - Vague disclaimers like "results may vary" are likely to be insufficient.

Testimonials and Expert Endorsements

- **3 Ways a Testimonial Can Be Deceptive:** (an example: weight-loss)
  1. Endorser may not have experienced the reported result.
  2. Weight loss may be attributable to other factors, such as diet, exercise, or lifestyle changes.
  3. If testimonial claiming extreme and atypical weight loss is presented as typical and ordinary, it is likely to be deceptive without an indication of the more modest weight loss results that the typical user would experience.

VENABLE LLP

Testimonials and Expert Endorsements

- **Expert Endorsements**
  - Experts qualifications must give the expertise he is represented as possessing.
  - An expert must have a reasonable basis for his/her opinion.
  - Expert's endorsement must be supported by an actual exercise of his expertise in evaluating the product features or characteristics with respect to which he is an expert and which are both relevant to an ordinary consumer's use of or experience with the product and are also available to the ordinary consumer.

VENABLE® LLP

What Does Your Study *Really* Show?

- Taking leaps in logic or “connecting the dots” is one of the most frequent mistakes companies make
  - Your study shows that the product does A
  - You know that A is associated with B
  - Therefore you claim that the product does B

  Ex: Study shows that product helps suppress cough, you know that coughing is associated with chest congestion, therefore you claim product reduces chest congestion.

VENABLE® LLP

Beware of These Areas:

- Website reviews posted by customers
- Social Media (e.g., Facebook pages)
- Guarantees

VENABLE® LLP

Guarantees

- Generally regulated by FTC
- “14-Day Money-Back Guarantee”
- “Try it for 14 days. If you are not fully satisfied, we will give you your money back.”
- “Guaranteed to see results in 14 days or your money back”

VENABLE LLP

Enforcement Trends

- FDA: Form 483s, Inflammation and Blood Sugar
- FTC: Enforcement against Health Claims and Weight Loss Claims
- State Attorney General Actions
- State Actions in California

FDA Enforcement Trend: Form 483s

- GMP violations
  - Over 35 issued from January 1st to early December 2013
    - **Popular Violations**:
      - Failed to establish specifications (21 CFR 111.70). [approx. 30]
      - Failed to qualify a component supplier by establishing reliability of the supplier's COA (21 CFR 111.75(a)(2)). [approx. 13]
  - Inspectors **cite 70%** of Dietary Supplement Firms
    - 444 out of 626 inspections for cGMPS resulted in issuance of Form 483 (2010-2012)
    - 116 dietary supplement firms received "official action" (WL) in 2012.
      - Anywhere from 2 to 58 violations cited.

VENABLE® LLP

FDA Enforcement Trend: Warning Letters re: Private Label Distributors

- "A firm that contracts with other firms to conduct certain dietary supplement manufacturing, packaging, and labeling operations for it is responsible for ensuring that the product is not adulterated for failure to comply with dietary supplement CGMP requirements, regardless of who actually performs the dietary supplement CGMP operations."
- Confirm they receive what they order from contract manufacturer or labeler.
  - "[T]o the extent that [company] manufactures dietary supplements on your behalf as a contract manufacturer, that your firm releases for distribution under your firm's name, your firm has an obligation to know what and how manufacturing activities are performed so that you can make decisions related to whether your dietary supplement products conform to established specifications and whether to approve and release the products for distribution." FDA, Warning Letter, Lumina Health Products, Inc. (Aug. 1, 2013).
- Perform finished batch identity testing.
  - "You are required to verify that either every finished dietary supplement batch or a subset of the finished dietary supplement batches that you identify through a sound statistical sampling plan meet the finished product specifications for identity, purity, strength and composition." FDA, Warning Letter, Precise Nutrition International, Inc. (July 11, 2013).

FDA Enforcement Trend: Warning Letters re: Inflammation Claims

2013 Examples:

- "Holm Oak (an ingredient in your product) … [a]nti-inflammatory and antibiotic properties." [Brower 9/9/2013]
- "It supports…the body's natural anti-inflammatory response." [Y.S. Health 8/29/13]
- "Grape seed extract contains polyphenols which have been shown in clinical studies to exhibit anti-inflammatory activity. … For example in a study conducted by the University of Rovira, in Spain, researchers concluded that Grape Seed Extract demonstrates a potential health benefit in inflammatory conditions…. " [Nature Cast Products 7/15/13]
- "[Product] is an all-natural herbal supplement known to reduce pain and inflammation…" [Entrenet 5/8/2013]

VENABLE® LLP

FDA Enforcement Trend: Warning Letters re: Blood Sugar Claims

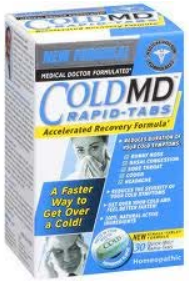
- FDA issued 9 WLs in June-July 2013 against companies marketing dietary supplements allegedly claiming to mitigate, treat, cure or prevent diabetes and related complications.
- How far is too far? Below are cited "disease" claims:
  - "Naturally control and maintain you blood glucose levels."
  - "Sugar Balancer"
  - "Lower blood sugar & A1c levels . . . ."
  - "[Product] not only helps to bring down the blood sugar level, it also helps repair β cells and restore the function of pancreas."
  - "Lessened total insulin needed."
  - "It has been proven by a research . . . to have similar effects to medicines used in diabetes treatment."
  - "NEW – Advanced Nutraceutical Stops This Silent Killer Before It Destroy[s] You . . . And those You Love!"

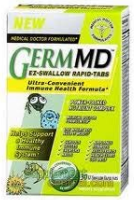
Enforcement Trends: FTC Enforcement against Health Claims

- **Nestlé Consent Decree (2010)**
  - FTC complaint charged that Nestlé made deceptive claims in ads that BOOST Kid Essentials (a probiotic) prevented upper respiratory tract infections in children, protected against colds and flu by strengthening the immune system, and reduced absences from daycare or school due to illness.
  - Nestlé entered into a Consent Agreement whereby it had to cease making such claims absent competent and reliable scientific evidence.

Enforcement Trends: FTC Enforcement against Health Claims

- **Iovate Settlement (2010)**
  - FTC charged Iovate Health Sciences U.S.A. with deceptively claiming in ads that dietary supplements Cold MD and Germ MD treated or prevented colds and flu, and that Allergy MD treated or prevented allergies and hay fever.
  - FTC also charged Iovate with deceptively claiming that weight-loss supplements Accelis and nanoSLIM caused weight loss and were clinically proven to do so.
  - Iovate settled with FTC for $5.5 million
    - Settlement also barred Iovate from making any disease claims unless the claim is approved by FDA and making any health related claims without competent and reliable scientific evidence.





VENABLE LLP

Enforcement Trends: FTC Enforcement against Health Claims

- In the Matter of POM Wonderful LLC, et al.(2013)
  - Background: FTC brought an enforcement action challenging claims made by Pom Wonderful in connection with its pomegranate juice and supplement products that the products will prevent or treat heart disease, prostate cancer, and erectile dysfunction.
  - Final Order: POM Wonderful LLC violated Sections 5(a) and 12 of the FTC Act. FTC stated two randomized, clinically-controlled trials are necessary to substantiate disease claims, and emphasized that the trials must show causation, contain control groups, examine variables that are predictive of disease, contain statistically significant results, and be double-blind.

Enforcement Trends: FTC Enforcement against Weight Loss Claims

- Jason Pharmaceuticals, Inc. (2012)
  - Complaint filed on FTC's behalf by DOJ alleging that company made unsupported representations since 2009 in radio, television, Internet and print advertisements that consumers would lose 2-5 lbs. per week and that company misrepresented that experiences of endorsers were typical.
  - Weight loss claims violated a 1992 FTC settlement order which barred it from making unsupported claims.
  - Consent Decree: Jason Pharmaceuticals will pay a $3.7 million civil penalty and is prohibited from making any representation that consumers can expect to achieve the endorsers' results, that the program will allow consumers to lose or maintain a certain weight, or that the program is safe or healthy, unless non-misleading and substantiated with competent and reliable scientific evidence, among other restrictions.

Enforcement Trends: FTC Enforcement against Weight Loss Claims

- Sensa, L'Occitane, LeanSpa, HCG Diet Direct (2014)
  - Part of FTC initiative "Operation Failed Resolution" to stop misleading claims for products promoting easy weight loss
  - Sensa to pay $26.5 million settlement: claimed "sprinkle, eat, and lose weight"
  - L'Occitane to pay $450,000: claimed skin cream would slim users' bodies
  - Order imposes $3.2 million judgment against HCG Direct because claimed that unproven hormone is weight-loss treatment
  - LeanSpa, LLC will surrender $7.3 million in assets: promoted acai berry and colon cleanse using fake news websites

VENABLE® LLP

"Resolutions to lose weight are easy to make but hard to keep… And the chances of being successful just by sprinkling something on your food, rubbing cream on your thighs, or using a supplement are slim to none. The science just isn't there."

Enforcement Trends: FTC Bureau of Consumer Protection Director Rich's Enforcement Priorities

- Jessica Rich Remarks "National Advertising Division Annual Conference" (September 30, 2013)
  - Deceptive Health Claims
    - FTC priority to investigate supplements, OTC drugs and foods claiming to cure diseases or improve health when they do not; claims that weight loss programs make you lose weight when they do not; or claims that a product or service achieves a health or safety result when not supported by evidence.
  - .Com Disclosures
    - FTC revised its .Com Disclosures guide to ensure that the same consumer protection laws that apply to commercial activities in other media apply online and in the mobile marketplace.
  - Collaborative oversight efforts with self-regulatory bodies.

FTC Enforcement Finds New Prey I

- Old Trend
  - Target blatantly false and deceptive claims (or those impossible to substantiate) with no or very weak substantiation.
    - "Lose 30 pounds in 30 days!"
    - "[Supplement] will make you look 10 years younger!"
    - "[Product] enables smokers to quit smoking quickly, effortlessly, and permanently."

FTC Enforcement Finds New Prey II

- New Trend
  - Target claims that are commonly accepted as true or having scientific merit.
    - Ingredients Targeted:
      - Calcium
      - Omega-3
      - Vitamin C
    - Types of Claims:
      - “Omega-3 promotes healthy brain development.”
      - “Selenium may reduce the risk of certain cancers.”

Has the FTC Changed the Rules for Substantiation?

- Adopted View of the FTC
  - "[M]arket analysts suggest that the downturn in the economy has actually led to increased spending on supplements as consumers attempt to manage their own healthcare and avoid expensive doctor visits and prescription medications. Given this trend, it is more critical than ever that the Commission work to ensure that consumers are getting truthful and accurate information, backed by solid scientific evidence, about dietary supplements." **Prepared Statement of the Federal Trade Commission on Deceptive Marketing of Dietary Supplements: FTC Enforcement Activities, Presented Before the Senate Special Committee on Aging** (May 26, 2010).
- Emerging FTC Standard in Consent Orders:
  1. Bar claims that a dietary supplement treats, cures, prevents, or mitigates disease **until approved by FDA** under its Nutrition Labeling and Education Act "significant scientific agreement" health claim review standard, 21 U.S.C. § 343(r)(5)(d).
  2. Require **two well-designed clinical trials** substantiating the claim at the time of first advertising to avoid a charge of deceptive advertising.
     - Double-blind, placebo controlled
     - Test whole product, not just ingredients
  3. Nonspecific Competent Reliable Evidence Requirement (the "Catch-all")

VENABLE® LLP

In the Matter of GeneLink, Inc.

Two Study Debate – Recent Development

Commissioner Ohlhausen Dissent (January 7, 2014)

"[The commissioners in the majority] impose an unduly high standard of at least two randomized controlled trials (or RCTs) to substantiate *any* disease-related claims, not just weight-loss claims. Adopting a one-size-fits-all approach to substantiation by imposing such rigorous and possibly costly requirements for such a broad category of health- and disease-related claims may, in many instances, prevent useful information from reaching consumers in the marketplace and ultimately make consumers worse off."

Enforcement Trends: State Attorney General Actions

- "Free" Claims
  - Ex. "First month of [product] free."
    - Wary of "negative option" sales.
- "Free Trials"
  - Do customers have to call to cancel within X days or their credit cards will be charged full amount?

VENABLE LLP

Enforcement Trends: State Attorney General Actions

- State AGs and County Attorneys may be active in policing false advertising claims

  Most Active State: California (both state and county)

  Multiple states may cooperate on larger investigations

  - Example--Enviga: Over 25 state AGs initiated an investigation into Coke, Nestle, and Beverage Partnership Worldwide alleging that calorie burning and implied weight loss claims made in connection with the green tea product, Enviga, were misleading -- settled for $650,000

Enforcement Trends: State Actions in California

- Regulatory Update: Prop. 65
- **AB 227:** CA Assembly voted to amend Prop. 65 by allowing certain small business owners 14 days to fix an alleged violation of the warning requirements. Applies to private citizen enforcement. (May 2013).
- **Governor seeking reforms (May 2013).**
  - End frivolous "shake-down" lawsuits
  - Improve how public warned
- **ERC continues submission of Prop 65 Notice of Violations involving Lead.**
- ***Environmental Law Foundation v. Beech-Nut Nutrition Corp*** **(Baby Food Trial)**
  - Rare: Only 9 out of 3,000 have gone to trial since 1986.
  - July 2013: Court ruled in favor of the defendant companies and held that any alleged exposures to lead in fruit juice and baby food products did not exceed the "safe harbor" level triggering a requirement to warn under Proposition 65. In doing so, the court ruled on a key issue that had not previously been litigated in any other Proposition 65 trial involving lead -- whether or not the "safe harbor" limit for lead exposure should be calculated on the basis of average exposure or maximum daily exposure.
- **BPA Delisted (April 2013)**

NAD & CRN Aggressive Initiative

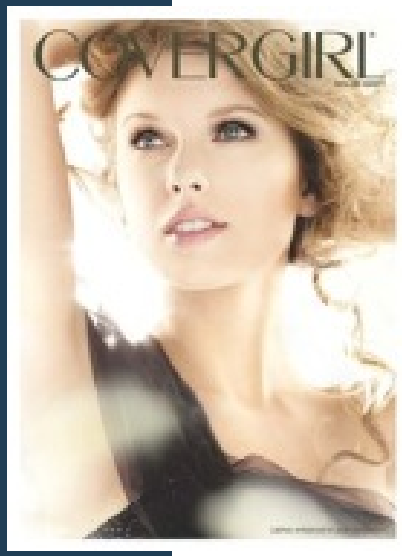
- Initiative begin in 2006 --- goal to **expand the review** of advertising claims for dietary supplements.
- Numbers:
  - 2009: 10 case reports
  - 2010: 27 case reports (out of 145 total!)
  - 2011: 21 case reports
  - 2012: 22 cases reports
  - 2013: 31 case reports
  - 2014: 1 case report so far
- Forward More Cases to FTC
  - "Nine times out of 10, we refer the advertising at issue to the [FTC], although we also refer cases to the [FDA]." – NAD spokeswoman
    - Agency gives cases high priority
  - What could this mean with the FTC's revised substantiation standard?

NAD Challenge Trend: Consumer Testimonials

- Heavy reliance on (and citation of) FTC's Revised Guides Governing Endorsements, Testimonials ("Revised Guides").
  - Use as basis for review.
  - NAD decisions often delineate permissible and FTC-compliant forms of advertising.
- *Health King Enterprise* –The NAD found that because there was no evidence that the product at issue had any effect on the condition described in the testimonial, it was "necessary and proper" for the advertiser to permanently discontinue the testimonial.
    - Note: NAD relied heavily on the deletion of the "results not typical" savings clause in the Revised Guides.

Post-Production Enhancement: NAD's Newest Attack

- Post-Production Enhancement
  - Just as NAD is targeting consumer testimonials, it is now also challenging post-production enhancement on beauty ads.
    - Launch inquiry into CoverGirl NatureLuxe Mousse Mascara--Discontinue post-production-enhanced photos of Taylor Swift.
    - Launch inquiry into CoverGirl Clump Crusher mascara--Discontinue use of artificial enhancements of eyelashes in mascara advertisements that make quantified performance claims: "NAD is simply restating what the law requires – that when you make a performance claim for mascara and include a photograph depicting a woman wearing the mascara, the picture should not be enhanced by artificial means – either digitally or physically."
  - **What does this mean for dietary supplement ads?**



VENABLE® LLP

Questions & Answers

VENABLE® LLP

Contact Information

Todd A. Harrison, Partner
taharrison@Venable.com
t 202.344.4724
f 202.344.8300

Claudia A. Lewis, Partner
calewis@Venable.com
t 202.344.4359
f 202.344.8300

Michelle C. Jackson, Counsel
mcjackson@Venable.com
t 202.344.4492
f 202.344.8300

Heili Kim, Counsel
hkim@Venable.com
t 202.344.4677
f 202.344.8300

John G. Moore, Counsel
jgmoore@Venable.com
t 202.344.4592
f 202.344.8300

www.Venable.com

VENABLE® LLP